

ANTIFUNGAL CREAM- antifungal cream

BluePoint Laboratories

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

1 % Clotrimazole Cream, USP

Active Ingredient

Active Ingredient Purpose

Clotrimazole 1.0% Antifungal

Purpose

- For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), Ringworm (tinea corporis).
- Relieves itching, scaling, cracking, burning, redness, soreness, irritation discomfort and chafing associated with jock itch.

Warnings

Do not use:

- on children under 2 years of age unless directed by a doctor.
- for diaper rash

When using this product

- Avoid contact with eyes.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 2 weeks, when used for the treatment of jock itch reaction develops
- there is no improvement within 4 weeks, when used for athlete's foot or ringworm.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Indications and Usage

- Clean the affected area and dry thoroughly. Apply a thin layer of cream over affected area twice daily (morning and night) or as directed by a doctor.
- Supervise children in the use of this product.
- For athlete's foot: Pay special attention to spaces between toes: wear well fitting, ventilated shoes, and change shoes and socks at least once daily.

Dosage and Administration

- For athlete's foot and ringworm, use daily for 4 weeks.
- For jock itch, use daily for 2 weeks.

- If condition persists longer, consult a doctor. This product is not effective on scalp or nails.

Keep Out Of Reach Of Children

KEEP OUT OF REACH OF CHILDREN

if swallowed, get medical help or contact a Poison Control Center right away.

INACTIVE INGREDIENTS

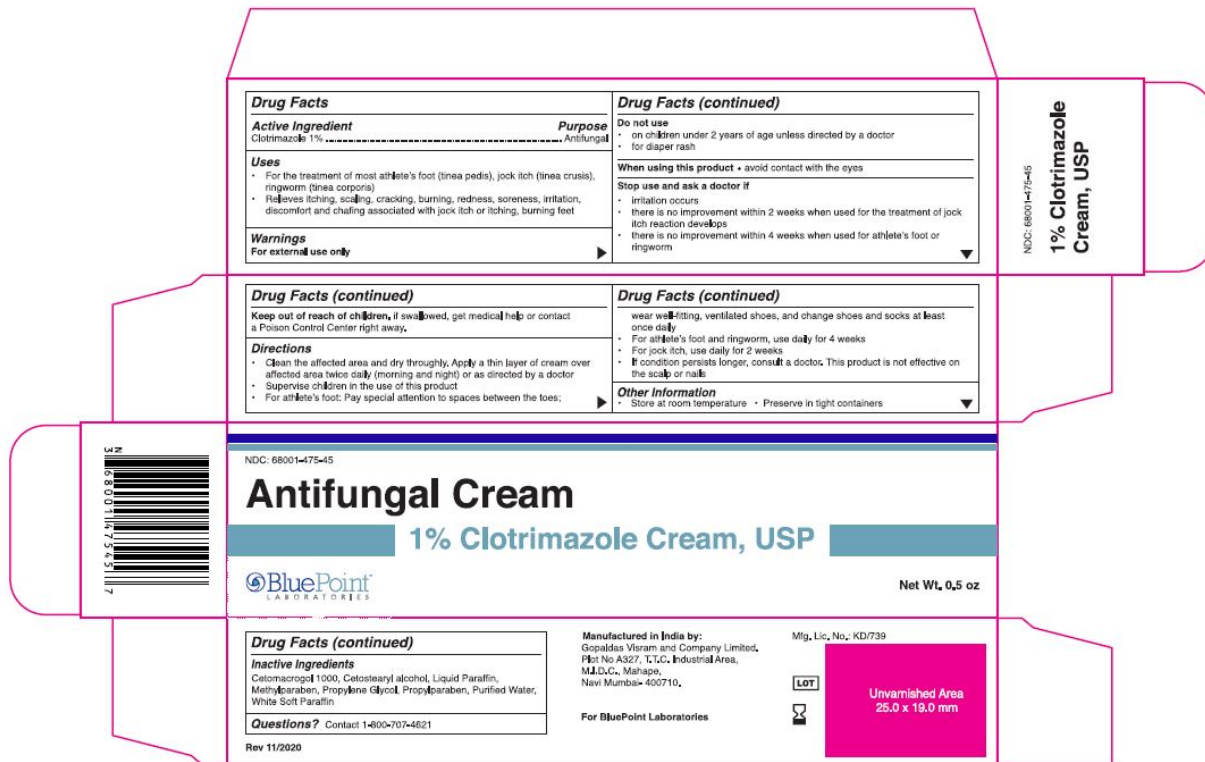
Inactive Ingredients: Cetomacrogol 1000, Cetostearyl alcohol, Liquid paraffin, Methylparaben, Propylene glycol, Propylparaben, Purified water, White soft paraben

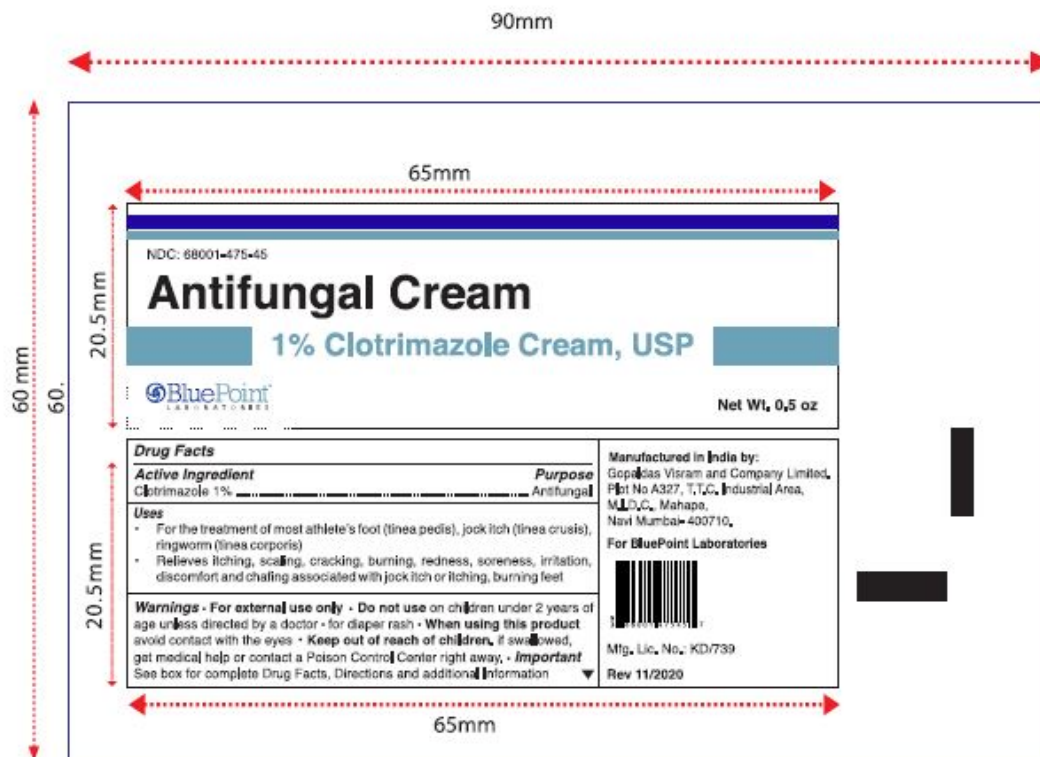
Contact 1-800-707-4621

- Store at room temperature
- Preserve in tight containers

Principal Display Panel

Size : L110 x w21 x h28mm





ANTIFUNGAL CREAM

antifungal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68001-475
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
PETROLATUM (UNII: 4T6H12BN9U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-475-47	1 in 1 CARTON	11/25/2020	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68001-475-46	1 in 1 CARTON	11/25/2020	
2		15 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:68001-475-45	1 in 1 CARTON	11/25/2030	
3		14 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part333C	11/25/2020	

Labeler - BluePoint Laboratories (985523874)

Establishment			
Name	Address	ID/FEI	Business Operations
Gopaldas Visram & Co., Ltd		858030888	manufacture(68001-475)

Revised: 11/2020

BluePoint Laboratories